DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 30 1988

Re: Ucephan
Docket No. 88E-0104

SOLICITOR

APR

U.S. PATENT AND TRADEMARK OFFICE

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,284,647 filed by Kendall-McGaw Laboratories, Inc. under the patent term extension provisions of 35 U.S.C. 156. The human drug product claimed by the patent is Ucephan (sodium phenylacetate and sodium benzoate), New Drug Application (NDA) 19-530.

Our previous correspondence with you stated that, according to a review of the Food and Drug Administration's official records, Ucephan, the product identified in the patent term extension application, was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). We also stated that our records indicated that Ucephan represents the first permitted commercial marketing or use of the active ingredients, sodium phenylacetate and sodium benzoate.

Additional information has revealed that Ucephan does represent the first permitted marketing or use of the active ingredient sodium phenylacetate, alone or in combination with another active ingredient. However, Ucephan does not represent the first permitted marketing or use of the active ingredient sodium benzoate. Sodium benzoate, and benzoic acid, the parent compound, have been marketed in 86 compounds. All of these products were approved during the period 09/19/38 - 06/26/53, and all approvals for all these products were withdrawn or discontinued during the period 10/31/61 - 12/09/83.

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d) we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Donald J. Bird
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